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APPLICATION NO	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO

EXAMINER

ART UNIT	PAPER NUMBER

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)
	09/519,271	HENDERSON ET AL.
	Examiner	Art Unit
	Shubo "Joe" Zhou	1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 February 2001*

2a)☐ This action is **FINAL** 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31* is/are pending in the application.

4a) Of the above claim(s) *8, and 19-31* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7, and 9-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claims *1-31* are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15)☒ Notice of References Cited (PTO-892)
16)☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17)☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). *2*
18)☐ Interview Summary (PTO-413) Paper No(s). _____
19)☐ Notice of Informal Patent Application (PTO-152)
20)☐ Other

DETAILED ACTION

Applicants' elections of Group I (claims 1-18), species "a peptide, restriction endonuclease or a transcription factor" from claim 7, and species "biotin-avidin complexes" from claim 16, in Paper No. 4, filed 2/20/01, is acknowledged. In Paper No. 4, applicant states that "applicant further elects specie group 1 from claim 6, i.e. a peptide, restriction endonuclease or a transcription factor". Since such specie is present in claim 7, not claim 6, and is among the species in claim 7 where the Examiner requires an specie election in the Office action mailed on 1/11/01, it is assumed that the phrase "claim 6" in applicant's statement is actually a typographical error and applicant means "claim 7". Furthermore, claim 8 will be treated as non-elected claim due to the fact that the critical limitation recited in the claim is "a duplex, a triplex, or a quadruplex performing legate", which is interpreted as "a duplex, a triplex, or a quadruplex forming nucleic acid molecule" as disclosed in the instant specification (page 15), and that applicant elects "a peptide, restriction endonuclease or a transcription factor", which are interpreted as non-nucleic acid molecules, as the sequence specific tags for the instant claims. Accordingly, claims 8, and 19-31 are withdrawn from further consideration as being drawn to non-elected inventions.

Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Specification

The specification is objected to because of the following:

The Brief Description of the Drawings in the specification refers to Figure 1, however, there is no such figure in the drawing as labeled such.

Also note the enclosed Notice of Draftperson's Patent Drawing Review".

Appropriate correction is required.

Claim Rejections-35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5, 7, 9-10, and 16-18 are rejected under 35 U.S.C. 112, second paragraph, as being unclear and confusing, for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 5 is confusing due to the phrase "wherein said scanning step the comprises...". Does applicant mean "wherein said scanning step then comprises..."?

The metes and bounds of claim 7 is not clearly set forth due to the recitation of a range within a range. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow

language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 7 recites the broad recitation a peptide, and the claim also recites a restriction endonuclease or a transcription factor, which is the narrower statement of the range/limitation.

Claims 9 and 16 are written as including apparent Markush groups. However, they are improper Markush claims and the metes and bounds of the claim is not clear due to the use of the phrase "selected from the group comprising...or...". It is unclear what else could be selected as a nucleic acid sample in the case of claim 9 or functional group in the case of claim 16, in addition to those that are recited. The proper form of a Markush group should recite members as being "selected from the group consisting of...and ..." See MPEP 2173.05(h).

Claim 10 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for lacking essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. Creating bar code is recited as an element of the analyzing step but it is not clear as to the relationship of the bar code and the analysis. Thus, it is unclear as to what information the bar code actually encompasses.

The phrase "nucleic sequences" in claim 18 is confusing. It is not clear what is meant by "nucleic sequences"? Does applicant actually mean "nucleic acid sequences"?

Claim Rejections-35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102(b) that form the basis for the rejections under this section made in this Office action:

> **A person shall be entitled to a patent unless –**
>
> **(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.**

Claims 1-4, 7, 9, and 11-14 are rejected under 35 U.S.C. § 102(b) as being anticipated by Pfannschmidt et al. (Nucleic Acids Research, 1996, Vol. 24, No. 9, pages 1702-1709).

Pfannschmidt et al. disclose a process of analyzing a nucleic acid sample comprising tagging sequence specific sites of the nucleic acid sample with a peptide; scanning the nucleic acid sample with a scanning force microscope (a NonoScope III multimode SFM by Digital Instruments, Santa Barbara, CA, which is known to artisans in the filed to be the same as atomic force microscope, which, in turn, is a form of scanning probe microscope); and analyzing the results of the scan of the nucleic acid sample (see page 1703-4, MATERIALS AND METHODS, and page 1702, ABSTRACT, especially note the phrase "protein tags" in the ABSTRACT). In this process, oligonucleotides-tagged with biotin bind to sample plasmid sequence-specifically and the biotin is bound by spreptavidin-alkaline phosphatase, which is peptide; thus the nucleic acid sample is tagged by a peptide sequence-specifically (see page 1703-4, MATERIALS AND METHODS). In the process, Pfannschmidt et al. also disclose that

the sample plasmid DNA is linearized with topoisomerase and *Alw*NI, which is known in the art to be a restriction endonuclease (see page 1703); that the linearized DNA sample is modified by being bound to oligonucleotides with biotin and the sample is deposited onto a deposition surface, a freshly cleaved mica surface, and the sample is dried with nitrogen (see page 1704, left column). The results of scanning force microscopy are shown in Figures 5 and 6 (see pages 1707-8).

Claim Rejections-35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> **(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.**

Claims 1-3, 5-7, 9, and 11-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pfannschmidt et al. (Nucleic Acids Research, 1996, Vol. 24, No. 9, pages 1702-1709) in view of Kajimura (US patent #: 5,760,300, Date of Patent: June 2, 1998).

As stated above, Pfannschmidt et al. disclose a process of analyzing a nucleic acid sample comprising tagging sequence specific sites of the nucleic acid sample with a peptide; scanning the nucleic acid sample with a scanning force microscope (a NonoScope III multimode SFM by Digital Instruments, Santa Barbara, CA, which is known to artisans in the filed to be the same as atomic force microscope, which, in turn, is a form of scanning probe microscope); and analyzing the results of the scan of the nucleic acid sample (see page 1703-4, MATERIALS AND METHODS, and page 1702,

ABSTRACT, especially note the phrase "protein tags" in the ABSTRACT). Pfannschmidt et al. do not disclose using a near field optical microscope, as required in the instant claim. Kajimura discloses "an atomic force microscope (AFM) or other similar instruments, for example, a scanning tunneling microscope (STM), a scanning near field optical microscope, etc." (see column 1). Obviously, atomic force microscope and near field optical microscope are art recognized equivalents for the same purpose. Thus, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made that one would have been motivated to combined the teachings of Pfannschmidt et al. and Kajimura to make and use the instant invention. Pfannschmidt et al. do not explicitly recite the term "computer". However, given that the microscope dislcosed in Pfannschmidt et al. is from Digital Instruments, Santa Barbara, CA, it would have been obvious to one of ordinary skill in the art that a computer would have been linked to such microscope for operation and analysis.

Claims 1-4, 7, and 9-14 are rejected under 35 U S C. 103(a) as being unpatentable over Pfannschmidt et al. (Nucleic Acids Research, 1996, Vol. 24, No. 9, pages 1702-1709) in view of Coles (US patent #: 5,314,829, Date of Patent. May 24, 1994).

As stated above, Pfannschmidt et al. disclose a process of analyzing a nucleic acid sample comprising tagging sequence specific sites of the nucleic acid sample with a peptide; scanning the nucleic acid sample with a scanning force microscope (a NonoScope III multimode SFM by Digital Instruments, Santa Barbara, CA, which is known to antisans in the filed to be the same of atomic force microscope, which, in turn, is a form of scanning probe microscope; and analyzing the results of the scan of the nucleic acid sample (see page 1703-4, MATERIALS AND METHODS, and page 1702, ABSTRACT, especially note the phrase "protein tags" in the ABSTRACT). Pfannschmidt

et al. do not disclose using bar code. However, Coles discloses creating and using bar code when atomic force microscopy is used in a method for imaging informational biological molecules (see columns 1 and 2). Since bar code is extremely commonly used in the art and in other fields for the reason of convenience, one of ordinary skill in the art at the time the claimed invention was made would have been highly motivated to combine the teachings of Pfannschmidt et al and Coles to create and use bar code in the analysis of scanning results, especially given that there is a lack of cooperative relationship between bar code and the rest of the analysis step in the instant claims, as set forth above.

Claims 1-4, 7, 9, and 11-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pfannschmidt et al. (Nucleic Acids Research, 1996, Vol. 24, No. 9, pages 1702-1709) in view of Rohr (US patent #: 5,445,971, Date of Patent: Aug. 29, 1995).

As stated above, Pfannschmidt et al. disclose a process of analyzing a nucleic acid sample comprising tagging sequence specific sites of the nucleic acid sample with a peptide; scanning the nucleic acid sample with a scanning force microscope (a NonoScope III multimode SFM by Digital Instruments, Santa Barbara, CA, which is known to antisans in the filed to be the same of atomic force microscope, which, in turn, is a form of scanning probe microscope; and analyzing the results of the scan of the nucleic acid sample (see page 1703-4, MATERIALS AND METHODS, and page 1702, ABSTRACT, especially note the phrase "protein tags" in the ABSTRACT). Pfannschmidt et al. do not disclose that the deposition surface is located on a dipstick. However, Rohr discloses using dipstick for the deposition of assay samples when atomic force microscopy is used in a assay using magnetically labeled binding members (see column 9, lines 2-15 and column 14, lines 12-22). In fact, a dipstick is listed as one of several

optional devices including a fiberglass. Obviously. dipstick is a functional equivalent to the silica tip disclosed by Pfannschmidt et al. Thus, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made one would have been motivated to combined the teachings of Pfannschmidt et al. and Rohr to make and use the instant invention, regarding using functional equivalents.

Conclusion

No claim is allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette. 1096 OG 30 (November 15. 1988). 1156 OG 61 (November 16, 1993). and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to:
Shubo "Joe" Zhou, Ph.D., whose telephone number is (703) 605-1158. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M

If attempts to reach the examiner by telephone are unsuccessful. the examiner's supervisor. Michael Woodward, Ph.D.. can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Patent Analyst Tina Plunkett whose telephone number is 703)-305-3524. or to the Technical Center receptionist whose telephone number is (703) 308-0196

S. "Joe" Zhou: sjz

Patent Examiner
April 24, 2001

ARDIN H. MARSCHEL
PRIMARY EXAMINER